UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/496,444	02/02/00	TAO	Y 1109

HM12/0228

Marianne H. Michel
Pioneer Hi-Bred International, Inc.
Corporate Intellectual Property
7100 N. W. 62nd Avenue P. O. Box 1000
Johnston IA 50131-1000

EXAMINER	
COLLINS, C	
ART UNIT	**PAPER NUMBER**
1638	6

DATE MAILED: 02/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/496,444	Applicant(s) TAO ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19, 22,-25 and 27-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,22-25 and 27-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-19, 22-25, and 27-53, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that examining all the inventions would not place an undue burden on the examiner because the inventions are sufficiently closely related. This is not found persuasive because while the search of Group I may overlap with the searches of Groups II-VIII, their searches are not coextensive of each other. In this particular instance, a search of Group I is not coextensive with the searches of Groups II-VIII because Groups II-VIII require searches for additional products and methods not claimed in Group I.

2. The requirement is still deemed proper and is therefore made FINAL.

Sequence Listing

3. Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

4. No Information Disclosure Statement has been filed in the instant application.

Drawings

5. No drawings were filed in the instant application.

Claim Objections

6. Claim 1 is objected to because of the following informalities: claim 1 (a) recites "a polynucleotide that encodes a polypeptide of SEQ ID NO:1", yet SEQ ID NO:1 is a nucleotide sequence rather than an amino acid sequence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-19 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. The claims are drawn to isolated nucleic acids encoding a plant cyclin E, or SEQ ID NO:1, or a polynucleotide amplified by primers of SEQ ID NOS: 3, 4, 5, and 6, and transgenic cells, plants, and seeds comprising said isolated nucleic acids. However, the specification does not set forth what specific structural or physical features define the claimed isolated nucleic acids and transgenic cells, plants, and seeds. The specification only discloses the nucleotide sequence of SEQ ID NO: 1 (sequence listing pages 1-3). The identities of the claimed isolated nucleic acids and transgenic cells, plants, and seeds are uncertain. One skilled in the art could not predict the structure and function of isolated nucleic acids comprising a polynucleotide amplified from a plant nucleic acid library using primers of SEQ ID NOS: 3 and 4 or 5 and 6, a polynucleotide having 20 contiguous bases of SEQ ID NO:1, a polynucleotide encoding a plant Cyclin E protein, a plant Cyclin E polynucleotide having at least 70% identity to the entire coding region of SEQ ID NO:1, or a plant Cyclin E polynucleotide that hybridizes under stringent conditions to SEQ ID NO:1. The physical features of the claimed isolated nucleic acids and transgenic cells, plants, and seeds cannot be ascertained in the absence of information about the functional activities of these nucleic acids. Additionally, the specification does not disclose the effect of incorporating the claimed isolated nucleic acids into the genome of a cell or plant.

10. The specification suggests a possible relationship between the SEQ ID NO:1 and Type E cyclins. However, the homology of predicted amino acid sequences to known proteins does not always predict the function of the homologous sequences (Doerks et al. 1998, Trends in Genetics, Vol. 14, No. 6, pages 248-250). Doerks et al. teach that incorrect or incomplete sequence information within a database affects the predictive capacity of the database (Page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (Page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (Page 248 column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (Page 248 column 3 fourth full paragraph).

11. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

> "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA ... Accordingly, the specification does not provide a written description of the invention ..."

12. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed isolated nucleic acids and transgenic cells, plants, and seeds, and given the high level of unpredictability in this art of determining the functions of these nucleic acids, one skilled in the art would not have been in possession of the claimed isolated nucleic acids and transgenic cells, plants, and seeds at the time this application was filed.

13. Claims 1-19, 22-25, 27-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

14. The claims are drawn to isolated nucleic acids, transgenic cells, plants, and seeds comprising said isolated nucleic acids. In the instant disclosure, applicants teach only the isolation of a cDNA that is SEQ ID NO:1 (Example 1 pages 44-46). Applicants also teach suggested methods for using the CycE gene to improve maize and soybean transformation, a suggested method for using the CycE gene to identify transformants without chemical selection, a suggested method for using the CycE gene under the control of tissue and/or cell specific promoters to confer a growth advantage on specific tissues and/or cells, and a suggested method for using the CycE gene during meristem transformation to reduce chimerism (Examples 4 and 5 pages 47-57, Example 6 page 57, Example 7 pages 57-58, Example 8 pages 58-59).

15. However, the specification does not provide any definitive evidence that SEQ ID NO:1 or a sequence comprising SEQ ID NO:1 encode a functional protein, such as stimulating cells to progress from the G1 phase to the S phase by introducing a nucleic acid comprising SEQ ID NO:1 into the cells. Although such a functional assay is suggested in the specification on page 46, it is unclear whether such a functional assay was in fact performed using a nucleic acid comprising SEQ ID NO:1. The specification does not set forth any specific structural or physical characteristics of any isolated nucleic acid comprising SEQ ID NO:1 that define its function, such as the identification of specific nucleotides whose alteration affects its ability to function in a cell cycle bioassay. In addition, applicants do not teach any examples of how to make a

transgenic host cell or plant comprising an isolated nucleic acid comprising SEQ ID NO:1. The specification does not provide any definitive evidence that introducing an isolated nucleic acid comprising SEQ ID NO:1. into a plant will result in any alteration of the plant's phenotype, such as the transformation of plant cells with a recombinant expression cassette comprising an isolated nucleic acid comprising SEQ ID NO:1. followed by regeneration and characterization of transgenic plants.

16. Guidance for making and using the claimed invention is necessary for enablement because the homology of amino acid sequences to known proteins does not always predict the function of the homologous sequences (Doerks et al. discussed *supra*). Guidance is also necessary for enablement because the ability of a particular nucleic acid sequence to alter the phenotype of a transgenic plant is highly unpredictable on the basis of nucleotide sequence information alone. Hemerly et al. teach transformation of *Arabidopsis* and tobacco plants with isolated nucleic acids encoding wild-type and mutant Cdc2a cell cycle regulatory proteins (The EMBO Journal, 1995, Vol. 14, No. 16, pages 3925-3936). Transformation of *Arabidopsis* with wild-type Cdc2a and with a Cdc2a mutant designed to accelerate the cell cycle unexpectedly did not affect the development of transgenic plants (page 3925 Abstract lines 9-12, page 3927 column1 paragraph 1 lines 15-18, page 3931 column 2 paragraph 3 to page 3932 column 1 paragraph 1 and column 2 paragraph 1). Transformation of *Arabidopsis* and tobacco with a Cdc2a mutant designed to arrest the cell cycle did affect the development of transgenic plants as expected (page 3925 Abstract lines 12-19, page 3927 paragraph spanning columns 1 and 2 to page 3929 column 2 1st full paragraph, page 3932 column 2 3rd full paragraph to page 3933 column 1). Because the function of an isolated nucleic acid comprising SEQ ID NO:1. has not

been demonstrated, and because the effect of transforming a plant with isolated nucleic acids comprising SEQ ID NO:1 is unknown, the claimed invention is not enabled by the specification in the absence of further guidance or example.

17. Given the unpredictability of determining the function of an isolated nucleic acid comprising SEQ ID NO:1 on the basis of its nucleotide sequence alone, the unpredictability of altering the phenotype of a plant by transforming it with an isolated nucleic acid comprising SEQ ID NO:1, the absence of guidance in the specification for making and using nucleic acids comprising SEQ ID NO:1 and transgenic host cells, plants, and seeds, the lack of working examples, and given the breadth of the claims which encompass multiple nucleic acid sequences comprising SEQ ID NO:1 as well as transgenic host cells, plants, and seeds comprising said nucleic acid sequences, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 101

18. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

19. Claims 1-19 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial utility. The claimed DNA sequences, cells, plants, and seeds are not supported by a specific asserted utility because the disclosed use of isolated nucleic acids comprising SEQ ID NO:1 to transform plants is generally applicable to the use of any isolated nucleic acid sequence to transform any plant, and therefore is not particular to the products and methods being claimed. The claimed DNA sequences, cells, plants, and seeds are not supported by a substantial asserted utility because no specific functional activities for the

claimed sequences have been established. There is no specific or substantial use for cells, plants, or seeds that comprise the claimed sequences. It would require additional research to establish the utility of the claimed DNA sequences, cells, plants, and seeds.

20. Claims 18 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

21. Claims 18 and 19 are drawn to seeds, but are not limited to seeds that comprise the construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene introduced into the parent plant would only be transferred to half of the seeds of that plant. In addition, given that there is no indication that there would be any other distinguishable characteristics of the claimed seeds, it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to recite that the seeds comprise in their genome the construct that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kende et al. (Genbank Accesssion X82035, 26 November 1996). The claims are drawn to an isolated nucleic acid comprising a polynucleotide having 20 contiguous bases of SEQ ID NO:1, a polynucleotide

encoding a plant Cyclin E protein, and a plant Cyclin E polynucleotide that hybridizes under stringent conditions to SEQ ID NO:1. Kende et al. teach. an isolated nucleic acid comprising a polynucleotide having 20 contiguous bases of SEQ ID NO:1, a polynucleotide encoding a plant Cyclin E protein, and a plant Cyclin E polynucleotide that would hybridize under stringent conditions to SEQ ID NO:1. Accordingly, claims 1-12 are anticipated by Kende et al.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

Cynthia Collins
February 22, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800